

AT



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,274	02/02/2001	Mireille Lamberty	A33595-PCT USA	3555

21003 7590 04/29/2004

BAKER & BOTTS
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,274

Applicant(s)

LAMBERTY ET AL.

Examiner

Samuel W Liu

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 February 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,6-19,22 and 46-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,6-19,22 and 46-55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-4, 6-19, 22 and 46-55 are pending.

Applicants' amendment filed 6 February 2004, which cancels claims 5 and 20-21, and amends claims 1, 8, 11-12, 14-15 and 19 and adds claims 47-52 have been entered. Note that claims 23-45 are canceled by applicants' amendment filed 1 August 2003.

The following Office action is applicable to the pending claims 1-4, 6-19, 22 and 46-55.

Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

Foreign Priority

The translation of the application France98/04933 (filed 6 February 2004) has been received and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 11, 14, 50 and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed.

This is a New Matter rejection for the following reasons:

Art Unit: 1653

The amended claim 1, the recitations as follows (i) “Xad represents a variable number of amino acid residues consisting essentially of ...”; (ii) “Xad” represents a variable number of amino acid residues comprising ...”; (iii) “Xae represents a variable number of amino acid residues consisting essentially of ...”; and (iv) “Xag represents or a variable number of amino acid residues consisting essentially of ...” represent departure from the specification and the claim as originally filed. Note that the new recitation “a variable number of amino acid residues” is a broad limitation which has not been set forth or/and described in the specification.

The amended claim 7, the recitation “Xac comprises at least one amino acid” represents a departure from the specification and the claims as originally filed since there is no support can be found in the specification for said recitation.

The amended claim 11, the recitations as follows: (i) “Xaa’ represents ... or a variable number of amino acid residues comprising ...”; (ii) “Xaa” represents a variable number of amino acid residues comprising ...”; (iii) “Xab’ represents a variable number of amino acid residues comprising...”; (iv) “Xae’ represents a variable number of amino acid residues comprising...”; and (v) “Xag’ represents ... or a variable number of amino acid residues comprising ...” represent departure from the specification and the claim as originally filed. Note that the new recitation “a variable number of amino acid residues” is a broad limitation which has not been set forth or/and described in the specification.

The amended claim 14, the new recitation “extracellular or subcellular localization in a host organism” represents a departure from the specification and the claim as originally filed because the specification does not set forth that the C- or/and N-end of the claimed peptide comprising peptide extension(s) is necessary for said extracellular or subcellular localization.

The new claim 50, the recitation "Xag represents ... or a variable number of amino acid residues consisting essentially of ..." represents a departure from the specification and the claim as originally filed. Note that the new recitation "a variable number of amino acid residues" is a broad limitation which has not been set forth or/and described in the specification.

The new claim 52, the recitations "Xaa' represents ... or a variable number of amino acid residues comprising ..." and "Xaa'' represents ... or a variable number of amino acid residues comprising ..." represent departure from the specification and the claim as originally filed. Note that the new recitation "a variable number of amino acid residues" is a broad limitation which has not been set forth or/and described in the specification.

Applicants' amendment file 6 February 2004 asserts that claims 47-55 contain no new matter (see page 9, the 1st paragraph), and that the amendment to the instant claims does not constitute the introduction of new matter (see page 14, lines 1-2). Applicants point to the specification at [0027] on page 6 for support for the newly amended claim 14. However, the specification does not appear to provide a clear support of the *extracellular localization* of the peptide, and "a variable number of amino acid residues". The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Claims 1-4, 6-19, 22 and 46-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in

Art Unit: 1653

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to describe, of the moieties: Xaa', Xaa''', Xab', Xac', Xag' and Xag of formula I set forth in the instant claim 1, each moiety represents a variable number of amino acid residues comprising (or consisting essentially of) the recited amino acid residues for each moiety. Thus, without written description, one cannot know what a variable number of amino acid is suitable for each moiety; thereby the peptide comprising moieties has antifungal activity. Thus, applicants are not in possession of an isolated peptide comprising said moieties having a variable number of amino acid residues.

This rejection can be overcome by adding functional language to the claims and reasonably define above-mentioned moieties so that one can correlate structure and function to determine if the peptide is taught in the specification and encompassed by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

In light of applicants submitting translation of the application France98/0493, the claimed priority based upon said France application is now considered valid; thus, the rejections under 35 USC 102 and 103 are withdrawn.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-

Application/Control Number: 09/673,274

Page 7

Art Unit: 1653

9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.

April 18, 2004

Karen Cochrane Carlson Ph.D.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER